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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,957	08/18/2006	Aida Inbal	06478.1508	2117

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EXAMINER	
ROOKE, AGNES BEATA	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,957	INBAL ET AL.	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This FINAL office action is in response filed on 06/10/2008.

Status of Claims

Claims 9-24 are pending and under consideration. The amendments to the claimed filed on 06/10/2008 has been acknowledged.

Objection Withdrawn

The objection to the specification has been withdrawn in view of the amendments.

Rejection Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Deisher et al. (WO 98/51333, international publication date 19 Nov, 1998; the reference is listed on the IDS document submitted on 08/18/2006).

Deisher et al. teach methods and compositions useful in treatment of reducing ischemic reperfusion injury and reducing necrotic tissue damage and/or vascular injury resulting from ischemic reperfusion by administration of factor XIII. See Example 1, and page 1, lines 9-16 (instant claims 9, 11, 14, 16, and claims 19-24 in reference to

diseases to be treated that are characterized by the presence of ischemic tissue, i.e. obstruction of the blood flow).

Deisher et al. teach methods for reducing ischemic reperfusion injury, reduction in tissue damage, vascular injury, myocardial infraction or stroke in a patient, wherein an effective amount of factor XIII is administered to a patient; and where the ischemic reperfusion injury addresses all diseases which are associated with disturbed blood perfusion and thus include instant claims that refer to stimulating the perfusion of ischemic tissues. See page 7, lines 25-28; page 9, lines 24-29; and page 11, lines 2-3; page 7, lines 10-17 (instant claims 9, 11, 14, 16, and 19-24 where all the diseases claimed suffer from disruption of a blood flow to the tissue, i.e. ischemia, for example).

Deisher et al. teach that the factor XIII composition is administered to the patient as a bolus injection. See page 7, lines 28-31 (instant claims 9, 11, 12, 14, 16, 17).

Deisher et al. teach that that the factor XIII composition can be administered as gels, foams or bandages [thus topical administration]. See page 8, lines 5-7 (instant claims 10, 13, 15, 18).

Further, the phrase in claims 9 and 14 in reference to a method of "stimulating the perfusion of ischemic tissues" is an intended use and it is not a limitation to the instant one step method. For, example, the court stated that the claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass*

Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). See MPEP 2111.02.

Therefore, in the instant case, the phrase "stimulating the perfusion of ischemic tissues" is only stating the purpose or the intended use for the invention, and it is not a claim limitation. Therefore, the claims are anticipated.

Applicants responded that claim 9 as amended addresses stimulating the perfusion of ischemic tissues, and that Deisher teaches methods for reducing ischemic reperfusion injury and does not teach stimulating the perfusion of ischemic tissues. Also, Applicants state that Deisher teaches the administration of Factor XIII after reperfusion of ischemic tissues in order to reduce ischemic reperfusion injury, and that claim 9 is directed to a method of initiating i.e. stimulating the perfusion of ischemic tissues.

Examiner responds that claim 9 is only a one step method, where Factor XIII is administered to stimulate the perfusion of ischemic tissues. Further, the stimulation step

is an intended use only. Also, claim 9 does not indicate whether Factor XIII is administered before or after reperfusion, but only states that stimulation occurs when Factor XIII is administered. Further, as it was cited in the original rejection, Deisher teaches methods of reducing ischemic reperfusion injury and diseases associated with disturbed blood perfusion thus including instant claims that refer to stimulating the perfusion of ischemic tissues.

Next, Applicants state that claim 14 refers to a method of stimulating the proliferation of new blood vessels in ischemic tissues, and that Deisher focuses entirely on the role of Factor XIII in blood coagulation, reducing blood loss, and preventing tissue damage after reperfusion, none of which relate to the use of activated Factor XIII for stimulating the proliferation of new blood vessels in ischemic tissues.

Examiner responds that Deisher teaches administration of Factor XIII to reduce tissue damage, ischemic reperfusion injury, and reducing blood loss and preventing tissue damage after reperfusion. Thus, reduction of blood loss can be achieved by stimulation of the proliferation of new blood vessels, for example. Further, it would be an inherent characteristic of Factor XIII to stimulate the proliferation of blood vessels when administered and thus an inherent mode of action of Factor XIII. Thus, administration of Factor XIII will inherently stimulate proliferation of new blood vessels.

Further, Applicants address the issue of intended use and state that since the phrase of stimulation of proliferation of blood vessels is no longer in the preamble, thus now it presents the inventive element of the invention that distinguishes the currently pending claims over the prior art.

Examiner disagrees and states that stimulation of the proliferation of a new blood vessels in ischemic tissues will inherently occur after the administration of Factor XIII, since as Deisher teaches, Factor XIII has been administered to reduce ischemic reperfusion injury, reduction in tissue damage, and reduction of blood loss, that can be achieved by stimulation of proliferation of new blood vessels, for example. Also, claims as rewritten, still indicate the intended use of Factor XIII.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656